

## REMARKS

This is in response to the Final Office Action mailed August 30, 2006. Claims 1-17 are pending in the application. Claims 5, and 12-17 are cancelled herewith. Thus, with entry of this Amendment, claims 1-4 and 6-11 are pending for consideration.

### ***I. Claim Rejections under 35 U.S.C. § 112, second paragraph***

Claims 12-17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants traverse this rejection. However, in further response, Applicants have cancelled claims 12-17, thereby rendering this rejection moot.

Claim 10 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. According to the Examiner, confusion exists as to whether Applicant is claiming a method for improving damage to an organ during an organ transplantation process, as the claim recites "***A method for*** suppressing or ***improving*** hypofunction of and ***damage to an organ*** during an organ transplantation process."

In response applicants herewith amend claim 10 for clarification. Applicants therefore respectfully ask the Examiner to enter this amendment and withdraw the current rejection.

### ***II. Claim Rejections - 35 U.S.C. § 103***

Claims 1, 3, 4, 6-12 and 14-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Patent Application Publication 05-038284

(hereinafter the Takama '284 publication).

The Examiner argues that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant application was filed to substitute for the starch ingredient present within the organ transplant preservation perfusion solution of the Wada '801 publication, a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides, for the alleged reason that not only is starch a polymer of glucose sugars, but also 1-ketose and nystose inulin fructan oligosaccharides are likewise polymers of glucose sugars, as well as fructose sugars, as reasonably suggested by the Takama '284 publication. The Examiner is of the opinion that one of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides within the preservation solution of the Takama '284 publication, for the starch ingredient within the organ transplant preservation perfusion solution of the Wada '801 publication, since a 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides are also useful for preserving live cells, as reasonably suggested by the Takama '284 publication. The Examiner also asserts that one of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in doing so since organs are simply an aggregation of a plurality of live cells having a specialized function.

The Examiner rejects claims 2 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Patent Application Publication 05-038284 (hereinafter the Takama '284 publication) and in further view of Japanese Patent Application Publication 07-099965 (hereinafter the Matsumoto '965 publication).

Specifically, the Examiner states that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant application was filed to incorporate for the 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides present within the organ transplant preservation perfusion solution of the Wada '801 publication, an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6; wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4, which is/are present within said composition for protecting live cells from frost damage, as reasonably suggested by the Matsumoto '965 publication.

The Examiner believes that one of ordinary skill in the art at the time the instant application was filed would have been motivated to substitute an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6; wherein said inulin fructan oligosaccharide and/or mixture of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1-kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4, which is/are present within said composition for protecting live cells from frost damage, as reasonably suggested by the Matsumoto '965 publication, for the 1-ketose inulin fructan oligosaccharide and/or a mixture of 1-ketose and nystose inulin fructan oligosaccharides present within the organ transplant preservation perfusion solution of the Wada '801 publication, since the Matsumoto '965 publication reasonably suggests that said composition is particularly useful for protecting live cells from frost damage, wherein said composition comprises: an inulin fructan oligosaccharide and/or a mixture of two or more inulin fructan oligosaccharides having a degree of polymerization of from 3 to 6; wherein said inulin fructan oligosaccharide and/or mixture

of two or more inulin fructan oligosaccharides is selected from the group consisting of: a 1 -kestose inulin fructan oligosaccharide having a degree of polymerization of 3; and a nystose inulin fructan oligosaccharide having a degree of polymerization of 4. Finally, the Examiner asserts that one of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in doing so since organs are simply an aggregation of a plurality of live cells having a specialized function.

Applicants respectfully but vigorously traverse the above rejections. First, the Examiner's case is built upon the assumption that all polymers of sugars are equivalent. Therefore, it would have been obvious to substitute one starch ingredient for another. Applicants disagree with this opinion. In fact, one of skill in the art of the invention would have known of many different types of polymers of sugars at the time of the invention. There were glucose, fructose, mannose, along with various ways to bind sugars to sugars within the polymer. For instance, trehalose is a polymer of glucoses obtained by binding glucose to glucose. Table 1 of the present specification shows that a composition comprising 1-kestose ( $GF_2$ ) or nystose ( $GF_3$ ) is actually superior to trehalose with respect to the preservation of organs. Thus, although many polymers of sugars were known, one could not predict which would have been effective for preserving organs.

The second assumption is that organs are equivalent to cells. According to the Examiner, organs are just aggregations of living cells with a specialized function. Applicants disagree with this assumption. In support of applicants' position, applicants point out that at the time of the invention, one of skill in the art would have known that although it was possible to preserve cells through freezing, it was not possible to preserve organs by freezing. Organs are to be preserved at low-temperatures with perfusion. It also was well-known that organs could not be preserved for as long as cells. While cells could be preserved for several decades or almost indefinitely, organs

could only be preserved for a number of hours. Thus, one of skill in the art would not have assumed that what was good for cells was also good for organs with regard to preservation. One would not have assumed that a suitable preservative for cells would be suitable for an organ. Arguable, cells are to organs, as are seeds are to trees. They are related but entirely different entities with different needs and functions. In view of this clarification, applicants respectfully request the Examiner to reconsider and withdraw this rejection.

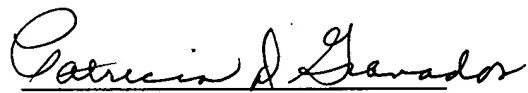
### CONCLUSION

In light of the above amendments and comments, Applicant respectfully requests that all rejections and objections be withdrawn and that a timely Notice of Allowance should be issued in this application. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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